

☐ FORM PTO-1390 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE (MODIFIED)

ATTORNEY'S DOCKET NUMBER

X16292

U.S. APPLICATION NO. (if known, see 37 C.F.R. 1.5)

10/566342

**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371**

INTERNATIONAL APPLICATION NO.  
**PCT/US2004/024386**

INTERNATIONAL FILING  
DATE 18 August 2004  
(18.08.2004)

PRIORITY DATE CLAIMED  
20 August 2003  
(20.08.2003)

**TITLE OF INVENTION: COMPOUNDS, METHODS AND FORMULATIONS FOR THE ORAL DELIVERY OF A  
GLUCAGON LIKE**

**PEPTIDE (GLP)-1 COMPOUND OR AN MELANOCORTIN 4 RECEPTOR (MC4) AGONIST PEPTIDE**

APPLICANT(S) FOR DO/EO/US: HERR Robert Jason, JUNGHEIM Louis Nickolaus, MCGILL John McNeill III, THRASHER Kenneth Jeff, VALLURI, Muralikrishna


Applicant herewith submits to the U.S. Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ The US has been elected (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ has been transmitted by the International Bureau.
  - c. ☒ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
  - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ have been transmitted by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☒ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A declaration of the inventors 35 U.S.C. 371(c)(4) was provided in the PCT Request Form.
11. ☐ A copy of the International Preliminary Examination Report (IPER), including any annexes, and, if not in English, an English language translation of the annexes to the IPER under PCT Article 36 (35 U.S.C. 371(c)(5)).

**Items 12. to 18. below concern document(s) or information included:**

12. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98. ☒ Search Report/Written Opinion (ISA/EP)
13. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
14. ☐ Assignment has been recorded at reel \_\_\_\_\_, frame \_\_\_\_\_.
15. ☒ A **FIRST** preliminary amendment.
- ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
16. ☐ A Sequence Listing, 1.821 Statement, and diskette.
17. ☐ A change of power of attorney with attachment.
18. ☒ Other items or information:

Please amend the first page of the specification by inserting the following cross-reference after the title:  
"This is the national phase application, under 35 USC 371, for PCT/US2004/024386, filed 18 August 2004, which, claims the benefit, under 35 USC 119(e), of US provisional application 60/496537, filed 20 August 2003"

|   |  |  |              |   |    |
|---|--|--|--------------|---|----|
| U.S. APPLICATION NO. (if known, see 37 C.F.R. 1.5)  |  | INTERNATIONAL APPLICATION NO.  |              | ATTORNEY'S DOCKET NUMBER  |    |
|   |  | PCT/US2004/024386  |              | X16292  |    |
| 10/566342   |  |  |              |   |    |
| 19.   | X  | The following fees are submitted:  |              | CALCULATIONS PTO USE ONLY   |    |
| (a)   | Basic national fee (37 CFR 1.492(a)).....\$300.00  |  |              | \$300.00  |    |
| (b)   | Examination fee (37 CFR 1.492(c))<br><br>If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).....\$0<br>All other situations.....\$200  |  |              | \$200.00  |    |
| (c)   | Search fee (37 CFR 1.492(b))<br>If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).....\$0<br><br>Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority.....\$100<br><br>International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB.....\$400<br><br>All other situations.....\$500 |  |              | \$400.00  |    |
| TOTAL AMOUNT (a + b + c) =  |  |  |              | \$900.00  |    |
| Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).  |  |  |              | \$  |    |
| CLAIMS  |  | NUMBER FILED   | NUMBER EXTRA | RATE  |    |
| Total claims  |  | 12-20=   |              | X \$50.00   | \$ |
| Independent claims  |  | 1-3=   |              | X \$200.00  | \$ |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable)   |  |  |              | + \$360.00  | \$ |
| TOTAL OF ABOVE CALCULATIONS =   |  |  |              | \$  |    |
| Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28).   |  |  |              | \$  |    |
| SUBTOTAL =  |  |  |              | \$900.00  |    |
| Processing fee of \$130.00 for furnishing English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).   |  |  |              | \$  |    |
| TOTAL NATIONAL FEE =  |  |  |              | \$  |    |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31).   |  |  |              | \$  |    |
|   |  |  |              | \$40.00 per property +  |    |
| TOTAL FEES ENCLOSED =   |  |  |              | \$900.00  |    |
|   |  |  |              | Amount to be refunded   | \$ |
|   |  |  |              | charged   | \$ |
| a.  |  | A check in the amount of \$_____ to cover the above fees is enclosed.  |              |   |    |
| b.  | X  | Please charge my Deposit Account No. 05-0840 in the amount of \$900.00 to cover the above fees. A duplicate copy of this sheet is enclosed.  |              |   |    |
| c.  | X  | The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 05-0840. A duplicate copy of this sheet is enclosed. |              |   |    |
| NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status. |  |  |              |   |    |
| SEND ALL CORRESPONDENCE TO:<br>ELI LILLY AND COMPANY<br>PATENT DIVISION<br>P.O. BOX 6288<br>INDIANAPOLIS, INDIANA 46206-6288<br>27 January 2006<br>Date<br>47.517<br>REGISTRATION NUMBER                  |  | Paula K. Davis<br>SIGNATURE<br>Paula K. Davis<br>317-433-3422<br>TELEPHONE NUMBER  |              | <br>25885<br>PATENT TRADEMARK OFFICE |    |

IN THE UNITED STATES RECEIVING OFFICE (USRO)

Applicant(s): Robert Jason HERR,  
Louis Nickolaus JUNGHEIM,  
John McNeill MCGILL III,  
Kenneth Jeff THRASHER,  
Muralikrishna VALLURI

International Application No.: PCT/US2004/024386

Filed: 18 August 2004 (18.08.2004)

Invention: COMPOUNDS, METHODS AND FORMULATIONS FOR THE ORAL DELIVERY OF A  
GLUCAGON LIKE PEPTIDE (GLP)-1 COMPOUND OR AN MELANOCORTIN 4 RECEPTOR  
(MC4) AGONIST PEPTIDE

Lilly Reference: X-16292

Earliest Priority Date: 20 August 2003 (20.08.2003)

**Certificate Under 37 C.F.R. § 1.10**

Attention: DO/EO  
Mail Stop PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir/Madam:

"Express Mail" mailing label number: E1 393133 040 US

Date of Deposit: 27 Jan. 2006

I hereby certify that the following attached paper or fee

Transmittal Letter to the United States Designated/Elected Office (US) concerning a filing under 35 U.S.C. 371 of the International Application identified above is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

QUEEN THOMAS  
(Typed or printed name of person mailing paper)

Queen Thomas  
(Signature of person mailing paper or fee)